

DEC - 1 2004

MX Polyaxial Pedicle Screw510(k) SummaryOctober 28, 2004Submitter

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 78284 Guyancourt  
 FRANCE

Contact person

J.D. Webb  
 1001 Oakwood Blvd  
 Round Rock, TX 78681  
 512-388-0199

Trade Name

MX Polyaxial Pedicle Screw

Common name

Posterior pedicle screw system

Classification name

Class II per 21 CFR section 888.3070

Product Code

MNI/MNH

Equivalent Device

The MX Polyaxial Pedicle Screw is a modification to the ISOBAR Polyaxial Pedicle Screw system (K013447) and the ISOBAR Closed Pedicle Screw (K020245). It is similar in material, design, and indications.

Device Description

The MX Polyaxial Pedicle Screw consists of pedicle screws and rods. Pedicle screws are inserted into the pedicles of the vertebrae and are available in three diameters ( $\varnothing 6.2$ ,  $\varnothing 7.0$  and  $\varnothing 8.0$ mm) and in lengths ranging from 35mm to 70mm. A rod is then inserted through an opening in the side of the head of the screw. A set screw is inserted through the top of the screw head. As the set screw is tightened the rod is secured in the screw head and the polyaxial mechanism is fixed in place. The rods are available in lengths ranging from 45-600mm.

The MX is fabricated from material that conforms to ASTM F136 (Ti-6Al-4V alloy).

Intended Use

The MX Polyaxial Pedicle Screw is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

As a pedicle screw system the MX Polyaxial Pedicle Screws are indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Summary of Nonclinical Tests

Testing was performed per ATM F1717.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC - 1 2004

Scient'X  
C/o Mr. J.D. Webb  
The OrthoMedix Group, Inc.  
1001 Oakwood Boulevard  
Round Rock, Texas 78681

Re: K043001  
Trade Name: MX Polyaxial Pedicle Screw  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: II  
Product Code: MNH, MNI  
Dated: October 28, 2004  
Received: November 1, 2004

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

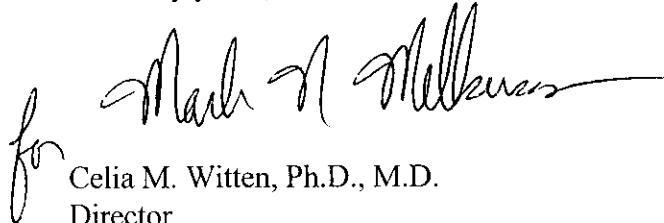
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. J.D. Webb

This letter will allow you to begin marketing your device as described in your Section 5 10(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



for  
Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K043001

Device Name: MX Polyaxial Pedicle Screws

Indications for Use:

The MX Polyaxial Pedicle Screw is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

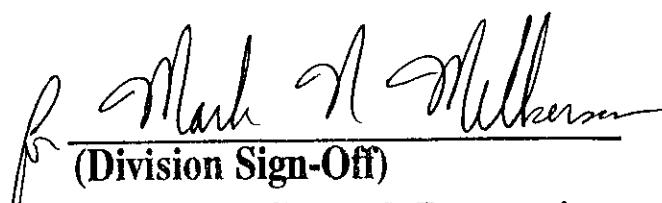
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Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Mark A. Millerson  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K043001